Enanta Pharmaceuticals Announces Nomination of Clinical Candidate EDP-235, its Lead Oral Protease Inhibitor Specifically Designed for the Treatment of COVID-19

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WATERTOWN, Mass.--(BUSINESS WIRE)-- Enanta Pharmaceuticals, Inc. (NASDAQ:ENTA), a clinical stage biotechnology company dedicated to creating small molecule drugs for viral infections and liver diseases, today announced the nomination of EDP-235, its lead oral protease inhibitor specifically designed for the treatment of COVID-19. Enanta plans to advance EDP-235 into the clinic early next year.

“The nomination of EDP-235 represents an important milestone for Enanta and highlights the strength of our experience in developing small molecule drugs for the treatment of viral infections at this critical time in the global fight against COVID-19,” said Jay R. Luly, Ph.D., President and Chief Executive Officer of Enanta Pharmaceuticals. “As the virus continues to rapidly mutate, there remains a need for an oral, direct-acting antiviral that potently inhibits viral replication. While vaccines and antibody therapeutics in development today target the viral spike protein, EDP-235 has been specifically designed to target conserved regions in the active site of a viral enzyme essential for SARS-CoV-2 replication, so we do not expect mutations in the spike protein to affect the activity of our candidate. We are encouraged by the promising preclinical data generated to date, which has demonstrated potent and selective inhibition of SARS-CoV-2, and we look forward to progressing EDP-235 into the clinic.”

EDP-235 potently and selectively inhibits SARS-CoV-2 replication in multiple cellular models, including primary human airway epithelial cells, with an EC90 of 33nM. EDP-235 retained activity against protease enzymes from currently circulating SARS-CoV-2 variants. Additionally, EDP-235 has a clean preclinical safety profile and has demonstrated a high barrier to resistance. Importantly, EDP-235 has excellent lung distribution in rats and demonstrates properties supportive of once daily oral dosing, in contrast to other protease inhibitors currently in development. Furthermore, EDP-235 has shown activity against other coronaviruses, providing the opportunity to potentially treat other infections that may emerge in the future.

Enanta expects to initiate a Phase 1 single and multiple ascending dose study to evaluate the safety, tolerability, and pharmacokinetics of EDP-235 in approximately 75 healthy volunteers in early 2022.

About Enanta

Enanta is using its robust, chemistry-driven approach and drug discovery capabilities to become a leader in the discovery and development of small molecule drugs for the treatment of viral infections and liver diseases. Enanta’s research and development efforts have produced clinical candidates for the following disease targets: respiratory syncytial virus (RSV), hepatitis B virus (HBV), non-alcoholic steatohepatitis (NASH) and SARS-CoV-2 (COVID-19). Enanta is also conducting research in human metapneumovirus (hMPV).

Enanta’s research and development activities are funded by royalties from hepatitis C virus (HCV) products developed under its collaboration with AbbVie. Glecaprevir, a protease inhibitor discovered by Enanta, is sold by AbbVie in numerous countries as part of its leading treatment for chronic HCV infection under the tradenames MAVYRET® (U.S.) and MAVIRET® (ex-U.S.) (glecaprevir/pibrentasvir). Please visit www.enanta.com for more information.

Forward Looking Statements Disclaimer

This press release contains forward-looking statements, including statements with respect to the prospects for further development of EDP-235 for SARS-CoV-2. Statements that are not historical facts, are based on management’s current expectations, estimates, forecasts and projections about Enanta’s business and the industry in which it operates and management’s beliefs and assumptions. The statements contained in this release are not guarantees of future performance and involve certain risks, uncertainties and assumptions, which are difficult to predict. Therefore, actual outcomes and results may differ materially from what is expressed in such forward-looking statements. Important factors and risks that may affect actual results include: the risks of early stage development efforts in the disease areas in Enanta’s research and development pipeline, such as COVID-19; the impact of development, regulatory and marketing efforts of others with respect to competitive treatments for COVID-19; Enanta’s limited clinical development experience; Enanta’s need to attract and retain senior management and key scientific personnel; Enanta’s need to obtain and maintain patent protection for its product candidates and avoid potential infringement of the intellectual property rights of others; and other risk factors described or referred to in “Risk Factors” in Enanta’s most recent Form 10-Q for the quarter ended March 31, 2021 and other periodic reports filed more recently with the Securities and Exchange Commission. Enanta cautions investors not to place undue reliance on the forward-looking statements contained in this release. These statements speak only as of the date of this release, and Enanta undertakes no obligation to update or revise these statements, except as may be required by law.

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